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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/730,704	12/08/2003	Ravi P. Nargund	21151	3989

210 7590 06/02/2006

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EXAMINER	
SPIVACK, PHYLLIS G	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 06/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/730,704	NARGUND ET AL.	
	Examiner	Art Unit	
	Phyllis G. Spivack	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-40 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-40 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Applicants' Response filed March 13, 2006 to the Request for Elections of Species for a pharmaceutical composition comprising 1) two appetite suppressants, 2) an appetite suppressant and a metabolic rate enhancer, 3) an appetite suppressant and a nutrient absorption inhibitor, 4) two metabolic rate enhancers, 5) a metabolic rate enhancer and a nutrient absorption enhancer, is acknowledged. Applicants elected composition species, for 1) two appetite suppressants, AM 251 and phentermine; for 2) an appetite suppressant and a metabolic rate enhancer, AM 251 and L-796568; for 3) an appetite suppressant and a nutrient absorption inhibitor, AM 251 and orlistat; for 4) two metabolic rate enhancers, L-796568 and theophylline; for 5) a metabolic rate enhancer and a nutrient absorption inhibitor, L-796568 and orlistat.

A suggestion for a Restriction Requirement is further noted. However, Restriction to one of the following inventions as required under 35 U.S.C. 121 is set forth below.

I. Methods and compositions comprising two active agents in the five categories *supra* in a method of treating diabetes; elevated plasma insulin concentrations; insulin resistance.

II. Methods and compositions comprising two active agents in the five categories *supra* in a method of treating obesity that is unrelated to diabetes; overeating; bulimia.

III. Methods and compositions comprising two active agents in the five categories *supra* in a method of treating hypertension.

IV. Methods and compositions comprising two active agents in the five categories *supra* in a method of treating dyslipidemia, hyperlipidemia.

V. Methods and compositions comprising two active agents in the five categories *supra* in a method of treating endometrial, breast, prostate and colon cancer; acute lymphoblastic leukemia.

VI. Methods and compositions comprising two active agents in the five categories *supra* in a method of treating osteoarthritis.

VII. Methods and compositions comprising two active agents in the five categories *supra* in a method of treating sleep apnea.

VIII. Methods and compositions comprising two active agents in the five categories *supra* in a method cholelithiasis; gallstones.

IX. Methods and compositions comprising two active agents in the five categories *supra* in a method of treating coronary heart disease, abnormal heart rhythms, heart arrythmias, myocardial infarction.

X. Methods and compositions comprising two active agents in the five categories *supra* in a method of treating polycystic ovary disease, GH-deficient subjects, metabolic syndrome, normal variant short stature, Frohlich's syndrome, Prader-Willi Syndrome.

XI. Methods and compositions comprising two active agents in the five categories *supra* in a method of treating craniopharyngioma, Turner syndrome.

The Groups are distinct, each from the other, for the following reasons:

The inventions as set forth are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case, the therapeutic modalities are

drawn to distinct organ systems. Further, the plethora of categories of drugs encompassed in the claim language essentially affects every organ system in the body, and the drugs demonstrate multiple pharmacologic effects.

The Groups have acquired a separate status in the art by their recognized, divergent subject matter. The searches required for each Group are not co-extensive resulting in an undue burden to the Examiner. Each Group is capable of supporting a separate patent.

Restriction for examination purposes as indicated is proper.

Should Applicants traverse on the ground that the species are not patentably distinct, Applicants should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicants are advised that to be complete, the reply to this requirement must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

A telephone call to the attorney is not required where: 1) the restriction requirement is complex; 2) the application is being prosecuted *pro se*; or, 3) the Examiner knows from past experience that a telephone election will not be made. See MPEP 812.01.

Where the Examiner has required restriction between product and process claims and Applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after Final rejection

are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the Examiner before the patent issues withdraws the restriction requirement. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached on 10:30 AM-7 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Phyllis Spivack

May 27, 2006

Phyllis G. Spivack

PHYLLIS SPIVACK
PRIMARY EXAMINER